DEPARTMENT OF DEFENSE

BREAST CANCER RESEARCH PROGRAM

CONCEPT AWARD

PROGRAM ANNOUNCEMENT

February 17, 2000

Headquarters, U.S. Army Medical Research and Materiel Command MCMR-PLF, 1077 Patchel Street Fort Detrick, Maryland 21702-5024

Concept Awards

I. Overview

I-A. History of the Congressionally Directed Medical Research Programs

Due to increased public awareness, the success of the Department of Defense (DOD) Congressionally Directed Medical Research Programs (CDMRP), and the work of grassroots advocacy organizations, Congress has appropriated monies directed toward specific diseases. Beginning in fiscal year 1992 (FY92), the U.S. Congress has directed the DOD to manage various extra- and intramural grant programs targeted toward specific research initiatives. The U.S. Army Medical Research and Materiel Command (USAMRMC) established the CDMRP to administer these funds. To date, \$1.5 billion has been targeted by Congress for research on breast, prostate, and ovarian cancer, neurofibromatosis, Defense women's health, osteoporosis, and other specified areas.

The CDMRP strives to identify gaps in funding and provide award opportunities that will enhance program research objectives without duplicating existing funding opportunities. A Program Staff composed of military and civilian scientists and clinicians manages the CDMRP. In addition, each program managed by the CDMRP convenes an expert Integration Panel (IP) of scientists, clinicians, and consumer advocates to deliberate issues, develop unique award mechanisms, and set an investment strategy.

I-B. History of the Breast Cancer Research Program

In 1993, a grassroots advocacy movement heightened political awareness of breast cancer as a major women's health issue. Federal budgetary opportunities spurred Congress to appropriate \$210M to the DOD budget for a peer-reviewed breast cancer research program. Since then, Congress has continued to appropriate money for breast cancer research managed by the USAMRMC. For FY92-99, Congress appropriated \$868.3M through the DOD for the Breast Cancer Research Program (BCRP), a multidisciplinary effort aimed at the eradication of breast cancer. The BCRP funds a diverse portfolio of research on prevention, detection, diagnosis, treatment, quality of life, and basic biology. A total of 1,806 grants have been funded by the BCRP from FY92-98 and 397 awards are currently being negotiated for the FY99 program. These awards have resulted in more than 2,400 publications in peer-reviewed scientific journals, more than 1,900 abstracts and/or presentations at scientific meetings, and 33 applications for patents or licensures.

II. Concept Awards

II-A. Concept Awards

To support the mission of the CDMRP to develop new and innovative means of expediting research, the BCRP will be executing a fast-track proposal submission, review, and negotiation process for Concept Awards. The intent of Concept Awards is to fund an initial concept or theory that could give rise to a testable hypothesis. These awards are to encourage the

exploration of untested, innovative questions in breast cancer. The proposal should represent a new paradigm in the study of breast cancer, challenge existing paradigms, or look at an existing problem from a new perspective. Proposals must describe how the new concept or theory will enhance existing knowledge of breast cancer.

Approximately \$3.5M of the FY99 appropriation has been set aside to support Concept Awards. Through this Program Announcement, the CDMRP is soliciting electronic submissions for short Concept Award proposals. Concept Awards can be requested for \$50,000 for direct costs over a 1-year performance period, plus indirect costs as appropriate. The receipt deadline is April 12, 2000. These awards will be reviewed and negotiated expeditiously so that investigators will have research dollars available no later than 30 September 2000.

Eligible applicants must have a masters or doctoral degree (e.g., M.S., M.A., Ph.D., D.Sc., D.N.S., M.D., D.O., etc.) from an accredited institution and access to the necessary space and equipment to perform the proposed studies. Eligible institutions include for-profit and nonprofit organizations, public and private, such as universities, colleges, hospitals, laboratories, companies, and agencies of local, state, and federal governments, including military laboratories. All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by an eligible institution. Award amounts are nontransferable and, if funded, will be made to the organization that provides required signatures as described in Section II-H.

II-B. Proposal Evaluation

The CDMRP uses a two-tiered review process for proposal evaluation, which consists of scientific merit review and programmatic review, as recommended by the National Academy of Science's Institute of Medicine. The two tiers are fundamentally different. The first tier is a peer review of proposals against established criteria for determination of scientific merit. The second tier is a programmatic review of proposals that compares submissions to each other and recommends proposals for funding based on program goals. Scientifically sound proposals that most effectively address the unique focus and goals of the program are recommended to the Commanding General, USAMRMC, for funding.

II-C. Scientific Peer Review – Evaluation Criteria for Concept Award Proposals

Scientific peer review will be conducted by expert panels composed of scientists, clinicians, and consumer advocates. Criteria used to evaluate Concept Award proposals will include: (1) innovation and novelty of concept/theory; (2) relevance to breast cancer; and (3) scientific merit and plan for testing the concept/theory. Proposals will be reviewed in accordance with these criteria and will receive an overall, global descriptor.

II-D. Programmatic Review – Evaluation Criteria for Concept Award Proposals

Funding recommendations made in programmatic review are based on a comparative process. The programmatic reviewers will consider how projects can lead to new insights into the etiology, prevention, detection, diagnosis, and/or treatment of breast cancer. The criteria used to make

funding recommendations will include: (1) ratings and recommendations of the peer review panels; (2) programmatic relevance; and (3) program portfolio balance with respect to research disciplines or specialty areas.

II-E. Proposal Forms and Questions

An electronic Concept Proposal Submission Form and these instructions can be downloaded from the CDMRP web site at http://cdmrp.army.mil/?/announce/. Alternatively, an electronic Concept Proposal Submission Form can be requested on disk by contacting the CDMRP at:

Phone: 301-619-7079 Fax: 301-619-7792

E-mail: cdmrp.pa@det.amedd.army.mil

Mail: Commander

U.S. Army Medical Research and Materiel Command ATTN: MCMR-PLF (BCRP99-Concept Awards)

1077 Patchel Street

Fort Detrick, MD 21702-5024

Questions concerning the preparation of proposals, formats, or required documentation can be addressed to the CDMRP at the above address. Applicants should submit any written questions regarding this program as early as possible. Every effort will be made to answer questions within 2 working days of receipt. Inquiries should be restricted to format issues only. Questions relating to technical proposal content or reasonableness/allowability of costs should be submitted in writing and will be forwarded to the U.S. Army Medical Research Acquisition Activity.

II-F. Proposal Preparation

After downloading the Concept Proposal Submission Form (see Section II-E), complete the form in accordance with the instructions. Please note, text limits are defined in characters; characters include spaces and punctuation. Text in excess of these limits cannot be entered in the form and will not be reviewed. Please note the following limits on length:

Proposal body – 5,500 characters (~1 page)

References – a limit of 5 references total, each reference limited to 225 characters (~3 lines) Principal Investigator Biographical Sketch – limited to 14,300 characters

Concept Awards are not intended to support ongoing work and the inclusion of the applicant's preliminary data is discouraged. Figures are not permitted and use of tables is discouraged.

The Concept Proposal Submission Form is in Microsoft Word and has been formatted to accept 12 point Times New Roman font. For symbols use either (1) the Windows Character Map (under Accessories) or (2) if text is prepared in a separate Word document, select Insert-Symbol...-(normal text). The use of other fonts is not recommended since the information may not be accurately transmitted. The Concept Proposal Submission Form has been set to accept a limited number of characters in each field. If a proposal is received in which the field limits have been altered, this proposal may be administratively disapproved and not forwarded for review.

If any difficulties occur when downloading this document or the Concept Proposal Submission Form, please contact the CDMRP at:

Phone: 301-619-7906

E-mail: cdmrpmaster@cdmrp.army.mil

no later than April 5, 2000 to receive assistance.

II-G. Proposal Submission

Upon completion, the Concept Proposal Submission Form should be saved using the following file name format: Last_FI_#.doc ("Last" indicates the PI's last name, "FI" indicates the PI's first initial, and "#" indicates the first, second, third, etc. Concept Award submission).

Investigators are encouraged to submit Concept Award proposals electronically. Please submit a Concept Award proposal using one of the two methods described below:

- 1. Via e-mail, as an attached file to bcrp99ca@cdmrp.army.mil by 10:00 p.m. Eastern Time (ET) April 12, 2000. In the subject line type "Concept Proposal Submission Attached." The CDMRP can guarantee the security of proposals upon receipt. Please note that a secure transmission also depends on the security of the sender's e-mail and network systems. Acknowledgment of e-mail proposal receipt will be sent via e-mail.
- 2. Via standard courier, on a 3 ½" computer disk, delivered to:

Commander

U.S. Army Medical Research and Materiel Command

ATTN: MCMR-PLF (BCRP99-Concept Awards)

1076 Patchel Street

Fort Detrick, MD 21702-5024

Information shipped via standard courier must be received by 4:00 p.m. ET April 12, 2000. Acknowledgment of standard courier proposal receipt will be sent via U.S. mail.

II-H. Proposal Review, Funding Notification, and Additional Information Required

Concept Award proposal review will be completed by June 2000 and investigators will be notified of funding decisions immediately.

Due to the need to complete award negotiations by September 30, 2000, investigators should submit the following information within 3 weeks of funding notification:

- A proposal cover booklet with required institutional signatures,
- A signed Certificate of Environmental Compliance, and
- The necessary Animal Use, Human Use, and Safety Requirements for the proposed project.

Specific information for preparing the above will be provided upon notification. Requirements for the above will be similar to those described in the March 3, 1999 BCRP Program Announcement available on the CDMRP web site at http://cdmrp.army.mil/?/announce/archives.html.